

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q101060

Masami KUSAKA, et al.

Appln. No.: 10/511,050

Group Art Unit: 1612

Confirmation No.: 6207

Examiner: MAEWALL, SNIGDHA

Filed: October 12, 2004

For: PREVENTIVE/REMEDIES FOR HOTFLASH

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on June 18, 2008 with Examiners Snigdha Maewall and Gollamudi Kishore:

REMARKS

An Examiner's Interview Summary Record (PTO-413) has not yet been received.

During the interview, the following was discussed:

1. **Brief description of exhibits or demonstration:** None
2. **Identification of claims discussed:** All pending claims.
3. **Identification of art discussed:** Furuya et al patents, Freedman, American Journal of Human Biology, The Lancet and Arch. Women's Mental Health, all of record.
4. **Identification of principal proposed amendments:** None.
5. **Brief Identification of principal arguments:** Applicants' representative argued that the teachings in the art show that the cause of hot flashes is not sex hormone-dependent

based on the references submitted with the Response filed June 11, 2008. It was also argued that even if hot flashes were considered to be sex-hormone dependent (a point Applicants do not concede), the compounds taught by the Furuya et al references are used for treatment of conditions that are caused, exaggerated or maintained by sex hormones and one of ordinary skill in the art would not have had a reasonable expectation of success of employing the compounds taught by Furuya et al for treating hot flashes, which are shown to occur under conditions where sex hormone levels are lowered.

Applicants also pointed out that the Furuya et al references teach that GnRH antagonists are known to have sex hormone lowering activity and therefore compounds having GnRH antagonist activity would not have been expected by those of ordinary skill in the art to be useful in the treatment of hot flashes, which is a condition that occurs when sex hormone levels are lowered.

6. Indication of other pertinent matters discussed: None.

7. Results of Interview: Examiner Kishore and Examiner Maewall indicated that they would carefully consider the arguments of record and the references submitted in view of Applicants' position when the case comes up for examination. No agreement was reached.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to

maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

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Date: June 20, 2008